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Useless Information: Genetic Patenting, the Usefulness Requirement, and the Effect on the "Big Freeze"

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I. INTRODUCTION

Patents are as much a part of business as a handshake or playing eighteen holes on a warm summer morning. They protect our ideas and give us protection while we desperately try to cultivate the fruits of our labor. They give innovators a fighting chance in a land of capitalistic juggernauts, and provide enough hope to encourage the little guy to pursue his dreams, to invent something new, or to make something else better. However, unlimited protection would be impractical and imprudent. Without a proper catalyst, some inventions are bound to fall short of their potential. Thus, a delicate balance must be struck in order to encourage innovators to continue doing what they do best while allowing, at the proper moment, those with the resources to take those innovations to the market to share with the rest of the world. The balance between profit and innovation must remain intact.

Over the years, the area of what is patentable has broadened considerably. Patents were originally given exclusively to protect tangible inventions. A person could not replicate a particular patented good without the permission of the patent holder. But, patents have proven to be adaptable and have changed along with the times. Advances in technology called for protection of intangible goods – protection of ideas or processes, methods of doing things better than the old way.[1] One thing had always remained the same: Patents were not to be granted on discoveries.

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[1] "As one academic has noted: 'IP is now implicated in routine, creative, communicative, and just plain consumptive acts that each of us perform everyday. The reach of the rights has been expanded just at the same moment that their practical effect has been transformed." *Genomics, and the Patenting of DNA: Review of potential implications for health in developing countries*, WORLD HEALTH ORG. 11 (2005), http://www.who.int/genomics/FullReport.pdf (citing JAMES BOYLE, SHAMANS, SOFTWARE & SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996).

This rule had always seemed clear enough: inventions, yes, discoveries, no. But we now enter into a time where the dichotomy between invention and discovery has become murky. Nature is being put to use.

The patenting of DNA presents an interesting point for consideration, because it is a topic about which there is great polarity in views, not only about its effects on research and access, but also due to more basic misgivings about whether DNA is the right sort of thing to patent.[2]

Natural things are being used in unnatural ways, and we, as a culture, are trying to handle this mash-up in the most practical of ways, without compromising the integrity of the patent system.

The patenting of genetic materials has brought forth many considerations. Not only has this practice caused us to reconsider the line where discovery ends and creation begins, but also several issues have arisen regarding the current patent standards used to determine when inventions can be patented. This note considers the current state of affairs regarding patentability in the field of biotechnology, especially that of genes and DNA.[3] Part II gives a brief background of patents in general, including the requirements that must be met for a patent to be granted, the way in which the patent process works, and the options available to a patent holder once a patent has been granted.[4] Part III explores the history of biotechnology patents.[5] Part IV takes a look at the relationship between patents and biotechnology, and sheds light on some of the common arguments both in favor of and against the patenting of genetic material.[6] Part V investigates solutions proposed to remedy the problems raised in Part III, and considers a different approach to fixing the patent system as

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[2] WORLD HEALTH ORG., *supra* note 1 at 48.

[3] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013). The human genome consists of approximately 22,000 genes packed into twenty-three pairs of chromosomes. Each gene is encoded as DNA, which takes the shape of the familiar "double helix" that doctors James Watson and Francis Crick first described in 1953. Each "cross-bar" in the DNA helix consists of two chemically joined nucleotides. *Id*.

[4] *See infra* Part II and accompanying notes 8-76.

[5] *See infra* Part III and accompanying notes 77-150.

[6] *See infra* Part IV and accompanying notes 151-197.

it relates to biotechnology.[7] Part VI concludes this note by proposing a slight adaptation to the existing patent system.[8]

II. BACKGROUND

A. What is a Patent?

"Patents were created as a way to provide financial incentives for inventors to undertake research, by allowing them to exclude competitors from exploiting their invention for a specified period of time."[9] Inventors are given a fair opportunity to commercialize and make profits as a result of their efforts.[10] Patent holders are given temporary rights that act as a fence blocking off others who try to access the subject of the patent without a license.[11] The primary objectives of the patent system are: (1) to encourage the disclosure of technological advances and findings to the public, and (2) to incentivize inventors by rewarding their efforts.[12] In the United States, patent protection arises from Congress's Constitutional authority "[t]o promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries."[13] Making use of this power, Congress enacted Title 35 of the United States Code, which governs all United States patent law.[14] There are four parts within the title.[15] Within those four parts, thirty-seven chapters with 376 sections can be found.[16] Part I establishes the United States Patent and Trademark Office

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[7] *See infra* Part V and accompanying notes 198-249.

[8] *See infra* Part V.

[9] WORLD HEALTH ORG., *supra* note 1 at 9.

[10] *See id*.

[11] *See id*.

[12] Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143 (2000).

[13] U.S. CONST. art. I, § 8, cl. 8.

[14] 35 U.S.C §§ 1-376.

[15] *Id*.

[16] *Id*.

(USPTO)[17] and gives the USPTO the powers necessary to run the United States patent system.[18] As defined by the USPTO:

A patent is a property right granted by the Government of the United States of America to an inventor 'to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States' for a limited time in exchange for public disclosure of the invention when the patent is granted.[19]

In other words, a patent holder is granted the sole right to exclude others from making, using, or selling an invention covered by the patent.[20] This right is often for a period of twenty years, assuming a request for renewal is properly filed and all applicable fees are paid on time.[21]

Patent applications are reviewed by the Patent and Trademark office to ensure that they meet all requirements, including patentable subject matter,[22] utility,[23] novelty,[24] and nonobviousness.[252627]

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[17] *Id*.

[18] *Id*.

[19] *General Information Concerning Patents,* UNITED STATES PATENT AND TRADEMARK OFFICE (Dec. 8, 2014 9:12 AM ET), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents.

[20] PATENT LAW BASICS § 6:1.

[21] *Id*.

[22] A patent is granted to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," subject to the additional requirements of the Patent Act. 35 U.S.C. § 101.

[23] "The utility of most *mechanical inventions* is apparent from an examination of their structures. Consequently, their utility (or, more precisely, their operativeness) is presumed." PATENT LAW BASICS § 8:6 (emphasis added). Some practical utility for the product of a *chemical process* must either be apparent to one skilled in the art or be disclosed in the specification for a patent application with claims directed to such process to satisfy the utility requirement. PATENT LAW BASICS § 8:7 (emphasis added).

[24] PATENT LAW BASICS § 7:1. "[35 U.S.C.A. § 102] sets forth the novelty requirement by spelling out just what types of activity negate novelty. It declares:

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country . . . or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or (c) he has abandoned the invention, or (d) the invention was first patented or caused to be patented, or was

Section 101 of 35 U.S.C. defines subject matter that is patentable.[28] A claim must fit in one and only one of four categories in order to be proper.[29] "These four categories of patentable inventions include manufacture, machine, composition of matter, and process."[30] Patentable subjects include products,[31] processes, products-by-processes, and living subject matter.[32] A product is a "new, useful and non-obvious machine, manufacture and composition of matter."[33] Processes are "new, useful and non-obvious way[s] of

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the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or (e) the invention was described in . . . (1) an application for patent . . . (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent . . . ." *Id*.

[25] An invention does not satisfy the nonobvious requirement

> if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains.

35 U.S.C.A. § 103 (a).

[26] Additionally, 35 U.S.C. § 112(a) refers to an enablement requirement. *The Enablement Requirement,* U.S. PAT. AND TRADEMARK OFF. (March 27, 2014 10:10:34),http://www.uspto.gov/web/offices/pac/mpep/s2164.html. "The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent." Id. Also, "In addition, the specification must provide a 'written description of the invention' disclosing sufficient information to enable one of ordinary skill in the art to make and use the invention, and must present the 'best mode' contemplated by the inventor for the design or operation of that invention." Dastgheib-Vinarov, *supra* note 12 at 150 (citing DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 71 (1998)).

[27] Becca Alley, *The Biotechnology Process Patent Act of 1995: Providing Unresolved and Unrecognized Dilemmas in U.S. Patent Law,* 12 J. INTELL. PROP. L. 229 (2004).

[28] 35 U.S.C. § 101.

[29] PATENT ACADEMY, PASSING THE PATENT BAR -A BASIC REFERENCE GUIDE, 227-229 (2013) (ebook)..

[30] *Id*.

[31] Product patents to cover, for example, chemicals, formulations, equipment and diagnostic kits. An invention covered by a product patent cannot be reproduced without a license, even if a different method is used to make it. See *Id*.

[32] *Id*.

[33] *Id*.

doing, making and using something."[34] A new process for creating a product may be patented even if the product itself is.[35] The opposite of this concept is found in product-by-process inventions, which occurs when a product is patentable, but the process is not.[36] "Living subject matter is patentable, but only if human ingenuity is used to invent the new matter."[37] If the living subject matter is not a result of human ingenuity, then the naturally occurring living subject matter may not be patented.[38] Today, the constitution of existing "in nature" is understood to be narrow in patent law in many countries.[39] "In nature" literally means what exists in nature; that is, what exists in its un-isolated form.[40] Methods in which things are accomplished, designs, and plants (to a certain extent) all fall within the range of patentability.[41]

Unpatentable material is classified as a discovery or some subject matter in which the novel aspects of which require mental activity.[42] This may include naturally occurring materials or organisms, or inventions encompassing a human being at its broadest reasonable interpretation.[43] Laws of mathematics, physics, and processes that depend on these laws are unpatentable.[44] Additionally, printed matter, methods of doing business, or mental processes are also unpatentable.[45]

Section 101 of 35 U.S.C requires a prima facie showing of utility prior to the granting of a patent.[46] "This showing must be

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[34] *Id*.

[35] PATENT ACADEMY, PASSING THE PATENT BAR -A BASIC REFERENCE GUIDE, 227-229 (2013) (ebook).

[36] *Id*.

[37] *Id*.

[38] *Id*.

[39] WORLD HEALTH ORG., *supra* note 1 at 10.

[40] *Id*.

[41] PATENT ACADEMY, PASSING THE PATENT BAR -A BASIC REFERENCE GUIDE, 227-229 (2013) (ebook).

[42] PATENT ACADEMY, PASSING THE PATENT BAR -A BASIC REFERENCE GUIDE, 237 (2013) (ebook).

[43] *See Id*.

[44] *See Id*.

[45] *See Id*.

[46] 35 U.S.C. § 101.

accompanied by sufficient evidence to support the utility, or usefulness of the material."[47] Additionally, it is required that the material be novel, or new.[48] "While all . . . requirements are necessary for patentability, many judges and scholars regard nonobviousness as the key requirement, in part, because it is frequently the most challenging to prove."[49] Obviousness has been determined on a case-by-case basis, and in making this determination the court must determine the scope and content of previous patents; differences between those previous patents and the patent at issue; and the level of skill involved in creating the patentable invention.[50] In layman's terms, the first paragraph of section 103 of 35 U.S.C. states that a new invention is not patentable if the invention would have been obvious to a person skilled in the art to which the invention pertains.[51]

B. Filing a Patent with the USPTO

The first step in the patent process is to conduct a patent search to determine whether an invention is likely to be able to be protected.[52] Inventions that have not yet been patented may be eligible for patentability.[53] Once it is determined that a particular invention has not yet been patented, the next step is to determine what type of application to file.[54] Applications may differ depending whether a design patent,[55] a plant patent,[56] or, most commonly, a utility patent[57]

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[47] PATENT ACADEMY, PASSING THE PATENT BAR -A BASIC REFERENCE GUIDE, 237 (2013) (ebook).

[48] *Id*.

[49] Dastgheib-Vinarov, *supra* note 12 at 151-52.

[50] *See infra* Part IV for proposed changes in the treatment of the nonobvious requirement in the field of biotechnology.

[51] *See Id*.

[52] Patents, *Patent Process Overview*, U.S. PAT. AND TRADEMARK OFF. (Nov. 24, 2014 2:40 PM ET), http://www.uspto.gov/patents/process/ppo_textonly.jsp.

[53] *Id*.

[54] *Id*.

[55] "[A] 'design patent' protects the way an article looks (35 U.S.C. 171). "Technology Center 2900, *Design Patent Application Guide*, U.S. PAT. &TRADEMARK OFF. (Aug. 13, 2012 10:42 AM ET), http://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/design-patent-application-guide#def.

is needed.[58] The text found in a patent must include "patent claims that define the subject matter of the invention, as well as all the elements, features and critical aspects of the invention, so that a person trained in the relevant scientific discipline should be able to replicate the invention."[59] The claims in the application define the patent's scope, or in other words, how expansive the protection that is given must be.[60] An additional consideration is the type of coverage that will be needed, for the process may vary depending on whether international or United States domestic protection is needed.[61] If filing in the United States, an individual seeking a patent must also decide whether a provisional[62] or a nonprovisional[63] application is most ideal.[64] Applications may then be filed pro se or through a registered attorney or patent agent.[65] After filing, the

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[56] "A plant patent is granted by the Government to an inventor (or the inventor's heirs or assigns) who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state." Technology Center 1600, *General Information About 35 U.S.C. 161 Plant Patents*, U.S. PAT. & TRADEMARK OFF. (Feb. 20, 2015 4:05 PM ET), http://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/general-information-about-35-usc-161.

[57] "In general terms, a 'utility patent' protects the way an article is used and works (35 U.S.C. 101)." Technology Center 2900, *supra* note 56.

[58] Patents, *supra* note 52.

[59] WORLD HEALTH ORG., *supra* note 1.

[60] *Id*.

[61] Patents, *supra* note 52.

[62] A provisional application for patent has a pendency lasting 12 months from the date the provisional application is filed. The 12-month pendency period cannot be extended. Therefore, an applicant who files a provisional application must file a corresponding nonprovisional application for patent (nonprovisional application) during the 12-month pendency period of the provisional application in order to benefit from the earlier filing of the provisional application. *Provisional Application for Patent*, U.S. PAT. & TRADEMARK OFF. (Jan. 12, 2015 2:11 PM ET), http://www.uspto.gov/patents/resources/types/provapp.jsp.

[63] A non-provisional patent application, once filed, merely establishes the filing date of the patent and begins the patent examination process. *Id*.

[64] Patents, *supra* note 52.

[65] *Id*. One major advantage to filing a pro se application is the avoidance of costly attorney's fees. Depending on the amount of technology involved in the patent, attorney's may charge anywhere form $5,000.00 to upwards of $15,000.00 to see the application process through. Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Apr.4, 2015),

USPTO examines the application to either grant or reject the application.[66] If rejected, the patent applicant may reply with a request to reconsider and may appeal as necessary.[67] Once granted, the applicant must pay an issue fee and a publication fee.[68] To preserve a patent for the years-to-come, maintenance fees are due three-and-a-half, seven-and-a-half, and eleven-and-a-half years after the original grant.[69]

C. Licensing patented inventions

Patent holders are given at least two choices as to how to exercise his or her exclusive rights.[70] "First, the patent holder may decide to be the sole user of the patented invention and exclude all others from its manufacture, use, or sale."[71] In the alternative, the patent holder may choose to grant a license to others, giving them "the right to use the invention under agreed-upon terms."[72] The patent holder may grant an "exclusive [license] to one licensee, or a non-exclusive license to several licensees."[73] "Exclusive licenses can include exemptions, for example for humanitarian or research use."[74] However a patent holder chooses to use the patent, "the patent holder is able to [create revenue either through the sale of the patented invention] and services, or through royalties obtained from licensees"

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http://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/.

[66] Patents, *supra* note 52.

[67] *Id*.

[68] *Id*. Patent application filing fees may range from $140.00 to $780.00. The major factor in determining the cost of a patent application is the complexity of the patent. Additional up-front fees and maintenance fees may result in a patent filing process that costs thousands of dollars. *USPTO Fee Schedule*, U.S. PAT. & TRADEMARK OFF. (Feb. 4, 2015 6:14 PM ET), http://www.uspto.gov/web/offices/ac/qs/ope/fee010114.htm#patapp.

[69] Patents, *supra* note 52.

[70] WORLD HEALTH ORG.*supra* note 1 at 13.

[71] *Id*.

[72] *Id*.

[73] *Id*.

[74] *Id*.

using the patent.[75] This is the financial incentive that makes up the foundation of patent law.[76]

III. THE FIELD OF BIOTECHNOLOGY

A. The Patentability of Biotechnology

"At its simplest, biotechnology is technology based on biology - biotechnology harnesses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet."[77] In the recent decades, the field of biotechnology has been stirring up much controversy in the patent word. "In recent years, this history has been marked by dramatic changes in the way that lawmakers and courts view and interpret the system."[78] Biotech generally concerns the application of cellular and molecular biology to make or modify products and processes for specific use.[79] Biotechnology brings unique challenges to the topic of patentability, as often biotechnology patents often operate within a grey area dealing with living organisms.[80] Traditionally, living organisms were truly only products of nature, and therefore remained unpatentable.[81] However, this is no longer the case since advances in science have resulted in the technology to modify and develop organisms.[82]

The manipulation of living or biologically active materially has contributed greatly to humanity,[83] especially with advances made in

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[75] WORLD HEALTH ORG.*supra* note 1 at 13.

[76] *Id*.

[77]*What is Biotechnology?*, BIOTECHNOLOGY INDUS. ORG., https://www.bio.org/articles/what-biotechnology (last visited Oct. 22, 2015).

[78] *Id*. at 11.

[79] *Cf*. 1 BIOTECHNOLOGY AND THE LAW § 1:1, Westlaw (database updated June 2015).

[80] Jake Gipson, *Patentable Subject Matter: A Myriad of Problems,* 65 ALA. L. REV. 815 (2014).

[81] *Id*.

[82] *Id*.

[83] "Since biotechnological processes are inherently low-energy and renewable, they are being utilized to provide solutions for some of the world's problems. In agriculture, the bacterium *Pseudomonas syringae* has been modified to impart frost

the agriculture and pharmaceutical fields.[84] For example, patents have been procured in order to diagnose patients with genetic mutations using deoxyribonucleic acid (DNA).[85] All genetic material is comprised of the biochemical substance known as DNA,[86] and this includes the genetic material found in all living organisms.[87] DNA is a double helix shaped molecule, made of two linear chains made from adenine, guanine, cytosine, and thymine nucleotide bases.[88] An ordered sequence of these nucleotide bases within the DNA, located in a particular position on a particular chromosome may constitute a gene.[89] These genes encode a specific functional product such as a protein.[90] "One of the challenges with respect to DNA is that it is an upstream tool for basic research (e.g. PCR[91]), a medically

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protection to plants by deleting a gene for a protein that nucleates ice crystal formation." Dastgheib-Vinarov, *supra* note 12 at 146. Also, "Industrial applications of biotechnology include engineering microorganisms to be used to clean up oil20 and chemical spills. Bioengineered biodegradable plastics offer solutions to the world's growing waste disposal problem." *Id*. at 147. "Medical benefits of biotechnology include the development of new drugs and enhanced production of old drugs that combat cancer, A.I.D.S., dwarfism, diabetes, hepatitis, and even aging." Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267, 272 (1995).

[84] *Biotechnology*, WORLD INTELL. PROP. ORG., http://www.wipo.int/patents/en/topics/biotechnology.html.

[85] Christopher Bergin, *Take Off Your Genes and Let the Doctor Have A Look: Why the Mayo and Myriad Decisions Have Invalidated Method Claims for Genetic Diagnostic Testing*, 63 AM. U. L. REV. 173, 177 (2013) ("[D]iagnostic patents have three basic steps: (1) obtaining a DNA sample from a patient, thereby establishing a providing, collecting, or obtaining step, (2) sequencing that DNA sample, and (3) comparing the patient's DNA sequence to other known wild-type and mutant strands to determine if the patient has a mutation."). *Id*.

[86] WORLD HEALTH ORG., *supra* note 1 at 2.

[87] www.genome.gov

[88] *Id*.

[89] *Id*.

[90] *Id*.

[91] "PCR (short for Polymerase Chain Reaction) is a relatively simple and inexpensive tool that you can use to focus in on a segment of DNA and copy it billions of times over. PCR is used every day to diagnose diseases, identify bacteria and viruses, match criminals to crime scenes, and in many other ways." *PCR*, LEARN GENETICS, (2015), http://learn.genetics.utah.edu/content/labs/pcr/.

valuable product (e.g. gene therapy[92]), as well as vital information about the molecular basis for disease."[93] The basis for studies to develop therapeutics, and for immediate use in laboratories, is therefore sometimes dependent on some individual patents.[94] One of the DNA's most significant contributions has been the pharmaceutical use of DNA to develop large-molecule proteins, such as insulin, growth hormone, growth factors, and blood-clotting factors, to treat serious diseases.[95] Additionally, DNA has embedded within it, information about the future of an individual's health.[96] "DNA genetic testing involves the analysis of DNA in order to determine the presence a gene associated with a particular disease."[97] These tests come in four general varieties: carrier testing[98], prenatal testing[99], diagnostic testing[100], and predictive testing[101].[102] It is clear, that the isolation of genes from DNA is a very valuable tool to the

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[92] "Gene therapy could be a way to fix a genetic problem at its source. By adding a corrected copy of a defective gene, gene therapy promises to help diseased tissues and organs work properly. This approach is different from traditional drug-based approaches, which may treat symptoms but not the underlying genetic problems." *What is Gene Therapy?*, LEARN.GENETICS (2015), http://learn.genetics.utah.edu/content/genetherapy/gtintro/.

[93] WORLD HEALTH ORG., *supra* note 1 at 48.

[94] *Id*.

[95] *Id*.

[96] *Id*.

[97] *Id*.

[98] "Carrier testing determines if the person tested, who does not himself have the disease, carries a gene for the disease. If two carriers have a child together, there is a high probability that their offspring will have the disease." *Id*.

[99] "Prenatal testing determines whether a fetus is affected with a genetic abnormality causing a particular condition. Embryos may also be tested during in vitro fertilization before being surgically implanted into the womb; this is called pre-implantation diagnosis. For technical reasons, the latter method is not widely practiced." WORLD HEALTH ORG., *supra* note 1 at 48.

[100] "Diagnostic testing determines whether the tested individual in fact has a particular genetic condition or a genetic predisposition for acquiring the condition later in life." *Id*.

[101] "Predictive testing determines the presence in asymptomatic individuals of an abnormal gene that will lead to a disease in the future, or of a genetic predisposition for acquiring the condition later in life, in interaction with environmental factors." *Id*.

[102] *Id*. at 4.

medical community.

The USPTO states that, "a patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature."[103] According to this view, what distinguishes a DNA sequence that exists naturally in a cell or organism from a patentable DNA sequence is that the former owes nothing of its existence to a human inventor, while the latter would not exist without some form however minimal of human intervention.[104]

Once an isolated gene has been deemed an "invention" for patent purposes, the gene sequence must still have some distinguishable utility, and some sort of invented step must be demonstrated to meet the nonobvious standard.[105] "In general, DNA patents claim at least one of the following four applications of DNA sequences: diagnostic testing, research tools or methods, gene therapy or methods, or the production of therapeutic proteins to be used as medicines."[106]

In some areas, there is evidence that an increase in the amount of patents has not been accompanied by a proliferation of medical applications.[107] Undoubtedly, the lag between patents and medical applications is in some ways attributable to the complex nature of the science, as well as to technical issues.[108] "[I]t is unclear how much is related, if only indirectly, to a failure of incentive mechanisms, including patents, to generate new and useful products and services."[109]

B. Ethical Objections

Many ethical concerns have been expressed regarding the modification of human biological material.[110] "It has been claimed that it is unacceptable for people to have 'proprietary rights in living

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[103] *Id*.

[104] WORLD HEALTH ORG., *supra* note 1 at 4.

[105] *Id*.

[106] *Id*.

[107] *Id*. at 48.

[108] *Id*.

[109] WORLD HEALTH ORG., *supra* note 1 at 48.

[110] *Id*. at 30.

beings and tissues,'[111] and that market logic now holds sway over the use of living organisms (or their component parts)."[112] *The United Nations Educational, Scientific and Cultural Organization's Declaration on the Human Genome and Human Rights* makes the claim that the human genome is the "common heritage of humankind."[113] This implies that DNA goes beyond existence as regular biological molecule, and that it also includes some sort of special character.[114] "Human DNA is common to all human beings (DNA itself is common to all living things), past and present. Therefore, DNA is foundational not only biologically, but also historically and even morally; in its' significance."[115]

Genetic material, in essence is knowledge and information, and typically knowledge and information is seen to be beneficial to the public.[116] "Genomics knowledge is nonrivalrous in consumption (not depleted by use), and is usually made public by genomics databases on the Internet and journal publication, as was the case with the malaria and mosquito genome."[117] "It is a global public good in the sense of the knowledge not being bound by national border, in discovery, transmission, or use. Further, the global public-good nature of genomics is reflected in the way in which the Human Genome Project was funded and undertaken."[118]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) leaves space for countries to do precisely this. According to Article 27 of TRIPS:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious

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[111] *Id*.
[112] *Id*.
[113] *Id*. at 31.
[114] WORLD HEALTH ORG., *supra* note 1 at 31.
[115] *Id*.
[116] *Id*. at 32.
[117] *Id*.
[118] *Id*.

prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[119]

C. Legal Issues

It is often argued that DNA, in certain cases, is not suitable as patentable subject matter when the legal requirements for patents are applied strictly.[120] One concern is that because genetic material is essentially information; therefore, DNA's value is primarily in the information within the material and not in the material qualities of the DNA itself.[121] Given this viewpoint, this represents a departure from patent doctrine, ". . . which is based on an agreement to disclose information in exchange for giving the inventors' rights over the material invention."[122] "If DNA itself has value not only as material, but also, if not primarily, as information, this moves away from the usual range of patentable material and presents a new challenge for those who need access to the information."[123]

In the first instance, there has been concern about the requirement of an "inventive step", given that the sequencing of DNA, once a laborious manual task, has become a highly automated and routine part of laboratory practice. In the United States, the Court of Appeals for the Federal Circuit's interpretation of the "non-obviousness" standard has explicitly denied that the difficulty or complexity of invention matters at all in the determination of patentability. Additionally, there has been questioning of the granting of patents for sequences of questionable or limited utility. Some of this controversy has abated with the USPTO's 2001 guidelines on expressed sequence tags (ESTs, short pieces of DNA that help to identify when particular genes are being expressed in cells), which tighten the specifications regarding what constitutes "utility".[124]

The amount of creative energy and the technical difficulty

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[119] *Part II — Standards concerning the availability, scope and use of Intellectual Property Rights*, WORLD TRADE ORG (2015) http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

[120] WORLD HEALTH ORG., *supra* note 1 at 10.

[121] *Id*.

[122] *Id*.

[123] *Id*.

[124] *Id*.

required to acquire this genetic knowledge may be the factor determining whether or not something may be patented.[125] Some consider that the isolation and sequencing of genetic material takes little creative energy and difficulty, and requires only a basic competence.[126] On the other hand, it may take great effort in order to identify the link between a disease and a particular gene depending on the "complexity of the interactions involved."[127]

D. Biotechnology and the "Big Freeze"

"Entities from industrialized countries currently hold 97% of all patents worldwide. The rise in patents in biotechnology has been particularly dramatic, climbing by 15% per annum from 1990 to 2000 at the UPTO."[128] The growth of patents in the biotechnology field has been heavily influenced by the public sector.[129] "For example, public institutions in Europe and the United States own 30% of all the patents for DNA sequences filed between 1996 and 1999."[130] And "start-up companies have a higher share of biotechnology patents than do large, established pharmaceutical companies."[131]

The most basic argument in favor of granting these biotechnology patents is, as applicable to all types of patents, simply that people are naturally entitled to the fruits of their labor.[132] Patents are arguably necessary to make innovation profitable because patents grant the opportunity for a patent holder to exclusively profit from her work.[133] Locating, isolating, and describing biomolecular matter requires considerable ingenuity, and, as a result, the biotech industry argues that, without strong patent protection, firms could not justify the risk, time, energy, and money necessary to create new pharmaceutical and

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[125] WORLD HEALTH ORG., *supra* note 1 at 36.

[126] *Id*.

[127] *Id*.

[128] *Id*. at 20.

[129] *Id*.

[130] WORLD HEALTH ORG., *supra* note 1 at 20.

[131] *Id*.

[132] Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics,* 22 B.C. ENVTL. AFF. L. REV. 267 (1995).

[133] *Id*.

agricultural products.[134] Additionally, companies argue that, if they are to continue producing new drugs and therapies for the treatment of disease, the public may be best served by allowing life forms and their structural components to be patented as inventions.[135] This protection may be particularly critical for start-up biotechnology companies that need to attract capital; for intellectual property is often the sole asset of the company.[136] A shift in the way in which organizations do research has been sparked by this rapid increase in biotechnology patents.[137]

According to a recent report by the Organisation for Economic Cooperation and Development: Not only have new types of inventions—software, genetic, and business methods—been deemed patentable by some patent offices, but the ability of patent holders to protect and enforce their rights has also increased, leading many to call the past two decades a pro-patent policy era.[138]

While the current system promotes innovation by rewarding innovators early in the developmental stages, this early reward "could hinder those conducting important research or providing needed services downstream, and can inhibit cumulative innovation."[139] This may be the result when licenses for patents granted prematurely restrict the amount of research that may be conducted.[140]

Those opposed to living material patents specifically oppose those patents granted on single-function genes.[141] Often, these single-function genes must be combined with other genes in order for research to progress, and this often creates a "freezing" effect on biotechnology research because permission must be granted before any previously patented genes may be used to further the research.[142] Thus, granting patents on genes when they are pre-market or while

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[134] *Id*.

[135] *Id*.

[136] *Id*.

[137] WORLD HEALTH ORG., *supra* note 1 at 11.

[138] *Id*. at 11-12.

[139] WORLD HEALTH ORG., *supra* note 1 at 12

[140] *Id*.

[141] Graeme Suthers, *Gene patents: "Discoveries not inventions"*, CANCER INSTITUTE NSW (Sep. 28, 2010), http://www.cancerinstitute.org.au/news-events/latest-news/gene-patents-discoveries-not-inventions.

[142] *Id*.

they are still upstream in the research process may be stifling life-saving innovations further downstream in the course of research and development.[143] Furthermore, the increased protection on genes may be raising the overall cost of research and development because a company that wishes to use the results of other research is bound to incur large costs in acquiring licenses to use other patents.[144] As a result, the field of biotechnology faces the "tragedy of the anticommons," where a resource is prone to underuse when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.[145] "This debate reflects a fundamental controversy about whether DNA ought to be treated specially, or the same as any other molecule."[146]

IV. The History Behind Gene Patents

In 1953, James Watson, Francis Crick, and Maurice Wilkins first discovered DNA and pulled at the first thread to unravel the mystery blanketing genetics and heredity.[147] This scientific leap was made possible by several scientific breakthroughs, including:

[P]rogress made by X-ray crystallographers in studying organic macromolecules; the growing evidence supplied by geneticists that it was DNA, not protein, in chromosomes that was responsible for heredity; Erwin Chargaff's experimental finding that there are equal numbers of A and T bases and of G and C bases in DNA; and Linus Pauling's discovery that the molecules of some proteins have helical shapes—arrived at through the use of atomic models and a keen knowledge of the possible disposition of various atoms.[148]

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[143] *Biotechnology*, World Intell. Prop. Org. (Feb. 2, 2015, 9:10 AM), http://www.wipo.int/patents/en/topics/biotechnology.html

[144] Graham Dutfield, *Intellectual Property and Basic Research: Discovery vs Invention*, SciDev (Jan. 05, 2003), http://www.scidev.net/global/policy-brief/intellectual-property-and-basic-research-discovery.html.

[145] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, Science, 698 (1998).

[146] World Health Org., *supra* note 1 at 18.

[147] James Watson, Francis Crick, Maurice Wilkins, & Rosalind Franklin, Chemical Heritage Foundation (2010), http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/biomolecules/dna/watson-crick-wilkins-franklin.aspx.

[148] *Id*.

Jointly, Watson, Crick, and Wilkins received the 1962 Nobel Prize in physiology or medicine for their contribution to science.[149]

In 1980, the Supreme Court held that a genetically engineered strain of bacteria "with markedly different characteristics from any found in nature" was patentable.[150] Patents for plants, animals, and micro-organisms such as cell lines and DNA became increasingly common, for Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development.[151]

A decade later, the Supreme Court of California provided the first clear rule regarding an individual's right to his or her own genetic material in *Moore v. Regents of University of California*.[152] In *Moore*, a leukemia patient underwent treatment at the UCLA Medical Center.[153] It was later discovered by the patient that his white blood cells had been used to create a cell line that would be used for the medical center's financial benefit.[154] When Regents of the university applied for a patent on the cell line,[155] the patient filed suit against his

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[149] *Id*.

[150] Diamond v. Chakrabarty, 447 U.S. 303 (1980). Patent examiners at the Patent and Trademark Office rejected Chakrabarty's patent application for a bacterium into which he introduced "naturally occurring plasmids" on the grounds that "(1) micro-organisms are nonpatentable because they are 'products of nature' and (2) living organisms are per se nonpatentable subject matter under section 101 of the Patent Act." Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1640 (2001). On appeal, the Supreme Court held in a five-to-four decision that a living, genetically altered organism may qualify for patent protection as a new "manufacture" or "composition of matter" under section 101 of the Patent Act. *Id*. at 1640-41. "[Chakrabarty's] micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Diamond*, 447 U.S. 303, 309-10, (1980) (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615, 7 S.Ct. 1240 (1887)).

[151] SCIDEVNET (2015) www.scidev.net.

[152] Moore v. Regents of Univ. of California, 793 P.2d 479 (1990).

[153] *Id*.

[154] *Id*.

[155] U.S. Patent No.: US4438032, 4,438,032 (filed Mar. 20, 1984)..

physician and the Regents of the University of California.[156] To the patient's dismay, the court found that the patient had no property rights to his discarded cells and was not entitled to any profits resulting from the cell line.[157]

A year later, biotechnology patentability broadened when the Federal Circuit upheld the patentability of human DNA sequences that are "purified and isolated" from the original object in nature.[158] Then in 1995, the United States Court of Appeals for the Federal Circuit ruled on a controversial issue in *In re Deuel*.[159] Deuel used uterine and placental cells to isolate the DNA and growth factor sequences of a protein called heparin-binding growth factor ("HBGF"). Deuel's claims were rejected for "obviousness" after the patent examiner and Board determined that the HGBF was the same as another protein, heparin-binding brain mitogen ("HBBM").[160] Deuel appealed the rejection.[161] The Court ultimately ruled in favor of Deuel, finding that, regardless of whether Deuel used the general method for isolating DNA or not, the location of the protein was not aided by the discovery of the prior HBBM.[162] Thus, the DNA molecules encoding the protein were nonobvious under section 103 of the Patent Act.[163]

In 1996, however, the patentability trend took a turn when the "Strategy Meetings on Human Genome Sequencing" resulted in an agreement that all raw sequence data from the human genome sequencing efforts should be "freely available [to] the public domain."[164] The organization that coordinated this effort was the Human Genome Organisation (HUGO).[165] "Partners in this initiative [have] articulated their commitment to making their results rapidly

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[156] *Moore*, 793 P.2d at 479.

[157] *Id*.

[158] Gitter, *supra* note 150, at 16331674 (citing Amgen v. Chugai, 927 F.2d 1200, 1206 (Fed. Cir. 1991)).

[159] *In re* Deuel, 51 F.3d 1552, 1554 (Fed. Cir. 1995).

[160] *Id*.

[161] *Id*.

[162] *Id*.

[163] *Id*.

[164] Peter J. Gardner, *U.S. Intellectual Property Law and the Biotech Challenge: Searching for an Elusive Balance*, 29 VT. B.J., 28 (2003).

[165] WORLD HEALTH ORG., *supra* note 1 at 5.

available, and to placing them in the public domain."[166] "British Prime Minister Tony Blair and then-President of the United States Bill Clinton issued a joint statement, affirming that: 'To realize the full promise of this research, raw fundamental data on the human genome . . . should be made freely available to scientists everywhere.'"[167] The patenting of DNA was not ruled out.[168] It was later added that "[i]ntellectual property protection for gene-based inventions will also play an important role in stimulating the development of important new health care products."[169] In the same vein, in 2001 the United States Patent Office revised its guidelines to emphasize that patents must show specific, substantial, and credible utility – a "real world context for using the invention."[170] The main driver of advances from the human genome was a project led by scientists all over the world called The Human Genome Project.[171] This project was "an approach to the large-scale sequencing and analysis of DNA that continues to have an enormous impact on how biomedical research is done in laboratories around the world."[172] Many similar projects seeking to sequence the genomes of many organisms have arisen from the Human Genome Project – "from useful laboratory animals to deadly disease-causing agents."[173]

Although "laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter under § 101 of the Patent Act,[174] "an

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[166] *Id*.

[167] *Id*.

[168] *Id*.

[169] *Id*.

[170] *See* Gardner *supra* note 164.

[171] WORLD HEALTH ORG., *supra* note 1 at 56. "So what, exactly, is the difference between genetics and genomics? As we have seen, medical genetics traditionally concerns itself with inherited single-gene . . . disorders, applying genetic tests, accompanied by non-directive counseling, to help patients in high-risk groups make decisions based on their genetic profile. What genomics brings is an approach to the large-scale study of many genes that permits sophisticated analysis of genes and their interactions. This means that genomics has applications far beyond simply genetic disorders; it can lead to greater understanding of the function of genes in more complex, multifactorial diseases and thereby to better therapies targeted more precisely at the root cause of disease." *Id*.

[172] *Id*. at 5.

[173] *Id*.

[174] Diamond v. Diehr, 450 U.S. 175, 185 (1981).

application of a law of nature . . . to a known structure or process may [deserve] patent protection."[175] In 2012, the Supreme Court affirmed in the biotechnology world that "(1) a newly discovered law of nature is itself unpatentable and (2) the application of that newly discovered law is also normally unpatentable if the application merely relies upon elements already known in the art."[176] In *Mayo Collaborative Services v. Prometheus Labs., Inc.*, the Court considered two method patents held by Promethium Labs for methods used to determine the appropriate amount of medication to administer to a patient with Crohn's Disease.[177] The Court conducted its inquiry by looking at each step described in the method[178] "to consider whether any of the steps added anything to the law of nature that was not

'well-understood, routine, conventional activity.'"[179] The "administering" step,[180] the "wherein" step,[181] and the final "determining" step[182] were all considered individually. The Court then evaluated the method as a whole to see if the method contributed anything new to the laws of nature.[183]

Most recently, the Supreme Court considered the validity of gene patents in *Association for Molecular Pathology v. Myriad Genetics,*

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[175] *Id*. at 187.

[176] Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLYO, http://patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.html.

[177], 132 S. Ct. 1289 (2012).

[178] Christopher Bergin, *Take Off Your Genes and Let the Doctor Have A Look: Why the Mayo and Myriad Decisions Have Invalidated Method Claims for Genetic Diagnostic Testing,* 63 AM. U. L. REV. 173, 177 (2013).

[179] *Id*. at 191 (quoting *Mayo* 132 S. Ct. 1289 at 1298).

[180] The "administering step "simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." *Mayo*,132 S. Ct. at 1297.

[181] "[T]he 'wherein' clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient." *Id*.

[182] "[T]he 'determining' step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use." Mayo Collaborative Servs. v. Prometheus Labs Inc.,132 S. Ct. 1297 (2012).

[183] *Id*. at 1298.

Inc.[184] Litigation in *Myriad* transpired from a global search to find the genetic basis for breast and ovarian cancer.[185] Myriad Genetics was founded in 1994 as a startup company out of University of Utah, by scientists involved in the hunt for the BRCA genes.[186] Later that year, Myriad filed the first patent for BRCA 1,[187] and within the next year, Myriad had isolated and patented a second gene associated with breast cancer, the BRCA2 gene.[188] Suit was filed against Myriad, seeking declaration that Myriad's BRCA1 and BRCA2 patents were not patentable subject matter under § 101 of Title 35 of the United States Code.[189] The primary plaintiff in the action was the Association for Molecular Pathology (AMP), which actively lobbied against the licensing and existence of gene patents.[190] AMP argued that the genes were unpatentable because they were products of nature that had merely been isolated,[191] and that no real world transformations occurred to the genes in the process of isolation.[192] The Court ultimately came to the holding that the process of isolating

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[184] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[185] J.M. Hall, et al., *Linkage of early-onset familial breast cancer to chromosome 17q21*. 250 SCIENCE 1684-89 (1990).

[186] Y. Miki,et al.,,*A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1*". 266 SCIENCE, 66–71 (1994).

[187] Patent No.: US6162897

[188] Patent No.: US5837492

[189] Myriad, 133 S. Ct. at 2107.

[190] ASSOCIATION FOR MOLECULAR PATHOLOGY, www.amp.org.

[191] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2119 (2013).. Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." *Id*.

[192] *Id*.

"As analyzed by the court, there were three distinct groups into which the claims fell for the purposes of its patentable subject matter analysis. The first group was composition claims that covered 'isolated' human genes (isolated DNA) of varying length and certain mutations in this DNA. The second group included all but one of the method claims, each describing a process in which a patient's DNA sequence was to be compared to the normal sequence to identify a predisposition to certain cancers. Finally, the third group consisted of a single method claim that disclosed a process to screen potential cancer therapeutics." Gipson, *supra* note 80 at 822

DNA involves naturally occurring segments of DNA, thus precluding patentability.[193] However, it also held that cDNA[194] is not naturally occurring and remains patent eligible.[195]

V. Analysis: Are We Looking in the Right Place?

A.The Nonobvious Requirement

In response to many of the issues that have arisen from gene patenting, and in proposing a solution, much attention has been given to the nonobvious requirement.[196] Whether an invention is obvious is determined by asking whether a person of ordinary skill in the art, who knew all of the invention's prior art, would have had a reasonable expectation that the invention would work.[197] In 1966 the Supreme Court in *Graham v. John Deer Co.* looked at multiple factors to determine whether an invention was obvious.[198] The analysis in *Graham* provided a step-by-step method of evaluating the

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[193] "It is undisputed that Myriad did not create or alter any of the genetic information encoded. . . . The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA." *Myriad,* 133 S. Ct. at 2116 (Thomas, J., majority opinion).

[194] cDNA refers to "complementary DNA" which is derived using the original DNA as a template. *See cDNA Production*, http://www.bio.davidson.edu/genomics/method/cDNAproduction.html.

[195] "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. . . . [The] creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring." cDNA "differs from natural DNA in that 'the non-coding regions have been removed.'" Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2119 (2013).

[196] *See* Dastgheib-Vinarov, *supra* note 12 at 143.

[197] *Id*. "The Federal Circuit applied this standard as a two-part test in In re Vaeck. The court said that a proper analysis under section 103 required consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Therefore, if a person of ordinary skill would have expected the invention to work, the invention is considered obvious and thus nonpatentable." *Id*. at 152.

[198] Ying Pan, *A Post-Ksr Consideration of Gene Patents: The "Obvious to Try" Standard Limits the Patentability of Genes*, 93 Marq. L. Rev. 285, 296 (2009).

nonobvious requirement.[199] First, differences in the prior art and the claims at issue are determined based on the scope and content of the prior art.[200] Then, the level of ordinary skill is resolved to determine whether the "subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."[201] The Court also noted that, to give light to the circumstances surrounding the origin of the subject matter, it might need to use "secondary considerations."[202]

These *Graham* factors remained in use from 1966 until 2007 when the Supreme Court once again considered the nonobvious requirement..[203] In that time, lower courts developed a "teaching, suggestion, or motivation" or "TSM" test that was to be applied aside from the *Graham* factors.[204] In application, courts contemplated whether there was a suggestion or motivation to combine known elements in prior art references.[205] The Supreme Court assessed the use of this TSM test in 2007 in a case called *KSR Int'l Co v. Teleflex, Inc.*,[206] holding that the TSM test was too rigid in application.[207] The Court held that "the fact that a combination was obvious to try might show that it was obvious under § 103,"[208] which led to the obvious to try standard that provides the background to obviousness as it relates to gene patenting.[209]

Much of the current patent law was developed between the Graham factors and the obvious to try standard.[210] Regarding the patenting of a naturally occurring gene, the Federal Circuit concluded in 1970 that "an unknown compound or composition of materials

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[199] *Id*. at 296-97.

[200] *Id*. at 297

[201] *Id*. at 298 (citing Patent Act § 103(a)).

[202] *Id*. at 297

[203] Pan *supra* note 198 at 298. In that time, "978 federal cases involved a determination of nonobvious, of which at least 688 adopted the Graham factors in their analyses." *Id*.

[204] *Id*.

[205] *Id*.

[206] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[207] Pan, *supra* note 198, at 299.

[208] *KSR*, 550 U.S. at 421.

[209] Pan, *supra* note 198 at 300.

[210] *Id*.

merely discovered from nature is not patentable."[211] In 1980, the Supreme Court in *Diamond v. Chakrabarty* allowed the patenting of a living organism.[212] The living organism had been genetically altered, and the Court noted that since "Congress intended statutory subject matter to 'include anything under the sun that is made by man,'"[213] a genetically modified organism was patentable as a "product of human ingenuity."[214]

In 1995, "[t]he Federal Circuit held in [*In re* Deuel] that a "DNA [in][w]hich the [p]rotein [p]roduct [i]s [h]omologous to a [k]nown [p]rotein [i]s [n]ot [o]bvious."[215] As discussed, Deuel had tried to patent a sequence that encoded a protein that was not known to anyone at the time.[216] However, there was a similar protein with a known function disclosed in previous experiments.[217] Because Deuel's sequence shared similarity to the sequence of the previously disclosed protein, the USPTO rejected the patent application for being obvious.[218] "[T]he court focused on a criterion familiar to old time chemists whose main way to design new compounds was molecular modification--structural similarity."[219] "[T]he court focused on the 'consequences of genetic code's redundancy on DNA's obviousness, asserting that it precludes contemplation and conception of the exact structure of cDNA molecules.'"[220] The Federal Circuit reversed the USPTO rejection by reasoning that "because of the redundancy in the genetic code, countless possible DNA sequences could code for the protein."[221] As a result, "a person

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[211] *In re* Bergstrom, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970). The court noted that compounds which exist in nature are not patentable, however, if a compound is isolated and that isolated compound is not found in nature, then the isolated compound is patentable subject matter. *Id*. at 1401.

[212] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[213] *Id*.

[214] *Id*.

[215] Pan, *supra* note 198, at 292.

[216] *Id*.

[217] *Id*.

[218] *Id*.

[219] Philippe Ducor, Recombinant Products and Nonobviousness: A Typology, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 43 (1997).

[220] *Id*.

[221] Dastgheib-Vinarov, *supra* note 12, at 155.

of ordinary skill in the art could not have determined the DNA sequence without actually doing the experiment performed in *Deuel*."[222] As it stands today, for naturally occurring DNA molecules, if their functions described in the patent applications agree "with the prediction based on its sequence homology to a protein with a known function, it is not patentable on the ground of nonobviousness."[223] But, if there is a discrepancy between the predicted function of a naturally occurring DNA molecule, as described in the patent application, and the function, as predicted based on its homology to a protein with a known function, it may meet the nonobvious standard.[224]

It is no surprise that there has been much concern involving the nonobvious standard. Granting exclusive rights to an obvious invention contributes significantly to the problems that coincide with gene patenting. Concern has been expressed that if the bar is set too low for achieving nonobviousness, then public fear regarding genetic privacy will result in fewer donations of genetic information that will hinder research and testing.[225] There are additional arguments in favor of a heightened standard for nonobvious that hinge on the availability of genetic information to researchers and scientists.[226] New strategies have been developed since the 1980's that make it easier to obtain cDNA and genes in the laboratory.[227] "[C]ompanies are using state of the art technologies from various fields to reduce the guesswork and increase the accuracy and certainty in performing previously lengthy recombinant DNA procedures."[228] Also, private

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[222] *Id*. "The court reasoned that 'the existence of a general method of isolating . . . DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.'" Pan, *supra* note 198, at 293.

[223] Pan, *supra* note 198, at 306.

[224] *Id*.

[225] Dastgheb-Vinarov, *supra* note 12, at 158.

[226] See *id*.

[227] *Id*. "In the past decade, a scientists, '[o]ne of ordinary skill in the art[,] [was able to] obtain a DNA sequence, once the protein coded for by that DNA [was] known, by (1) constructing a cDNA library, (2) designing an oligonucleotide probe, and (3) using the probe to screen the library.'" *Id*. (citing Anita Varma & David Abraham, DNA IS DIFFERENT: LEGAL OBVIOUSNESS AND THE BALANCE BETWEEN BIOTECH INVENTORS AND THE MARKET, 9 HARV. J.L. & TECH. 53, 59 (1996).

[228] *Id*. at 163

and public databases containing genomic research have become more readily available, making the "invention" of cDNA seemingly more obvious.[229] Freely accessible databases have been made available to the public by the government.[230] Some of these governmental databases "include the National Genbank, developed by the National Institutes of Health (NIH), and dbEST, the database for expressed sequence tags."[231] In the private sector, there are companies making money by charging for access to their sequenced gene databases.[232] To name a few: "Incyte, 'Sequana Therapeutics in San Diego, Millenium Pharmaceuticals in Cambridge, Massachusetts, and Myriad Genetics in Salt Lake City, Utah.'"[233]

Clearly, the degree of obviousness can interfere with the underlying principles which give rise to the social value of patenting.[234] The patenting of small molecules for drugs has been illustrative of this point.[235] At times, the degree of ingenuity behind an invention is overshadowed in valuations in favor of the time and money invested in the development of the invention.[236] "Patents, in this case, are principally to induce investment rather than to encourage innovation."[237]

Once the general population seemingly accepted the notion that genetic material may qualify as an invention opposed to a mere discovery, most of the attention has been aimed at adjusting the nonobvious standard to remedy the problems arising from gene patents. Though many great arguments have been presented, and many solutions have been recommended, nonobviousness is but one patent requirement. Directing our attention elsewhere, and perhaps assessing all facets of the system, may enable us to shed light on additional weaknesses within the current system – the correction of

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[229] *Id*. at 162.
[230] *Id*.
[231] *Id*.
[232] *Id*. at 163.
[233] *Id*. (citing Joan O'C. Hamilton, GET A LIFE, CAL LAW 39, 42 (1996).
[234] See WORLD HEALTH ORG., *supra* note 1, at 48.
[235] See *id*.
[236] See *id*.
[237] See *id*.

which may also help to alleviate the anxiety caused by genetic patenting.

B.The Uselessness of the Utility Requirement

As discussed, the main focus for those who want to better the current patent system has been on the nonobvious requirement. By no means should the nonobvious requirement be taken lightly. It is a very important aspect of the process and illuminates the policy behind granting patents at all. Strong arguments have been presented to adjust the nonobvious requirement, and progress has been made as a result of those arguments. Nonobviousness, however, is but one symptom to be treated in a greater illness. For purposes of this Comment, let us pretend that nonobviousness is a hurdle that has already been cleared, and now direct our attention to the usefulness of these genetic patents. Notwithstanding the other patent requirements, it appears that genetics patents that have been granted prior to the patented idea are ambiguous when it comes to their use. The usefulness requirement is being met on credit. Patentees are granted patents on ideas that show promise, but not utility, and this current system is contributing greatly to icing the momentum of innovation.

Two cases that illustrate this point are *Myriad* and *Chakrabarty*. Both cases involve patents granted for something that has been tweaked in the laboratory to make it different enough from the natural counterpart to qualify it for patent protection. Both cases were analyzed through the lens of the nonobvious requirement – that is, it was the Court's resolve to settle whether it was obvious to use naturally occurring materials in inventing something else. The end result in both was the same. The reasoning in *Myriad* is that, though DNA is found in nature, the cDNA for which a patent was sought is not. Thus, the cDNA met the nonobviousness requirement. Similarly, in *Chakrabarty*, though a bacterium was found in nature, the genetically modified bacterium for which the patent was sought was not found in nature. Therefore, the genetically modified bacterium was not obvious and was eligible for patent protection.

In *Chakrabarty*, the genetically modified bacterium was developed to treat oil spills, for the bacterium had been put to use and was capable of breaking down crude oil. Therein lies the key difference between the patent sought in *Chakrabarty* and the patent

sought in *Myriad* – the known usefulness of the invention. Take a moment to compare the language of the *Chakrabarty* patent to one of the patents at issue in *Myriad*. The Chakrabarty patent states that "[t]he versatility of these novel [bacterium] *has been demonstrated* by the substantial extent to which degradation of such complex hydrocarbons as crude oil and Bunker C oil has been achieved thereby."[238] Myriad's claim, on the other hand was that

[t]he present invention *relates generally* to the field of human genetics. Specifically, the present invention *relates* to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer. More specifically, the present invention *relates* to germ line mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast and ovarian cancer.[239]

The difference is clear that, from the language of the patents, *Myriad* had not proven the usefulness of the BRCA1 gene. The patent was applied for based on a known affiliation with breast cancer, but only a presumption that the BRCA1 would be useful in its treatment. It may be true that the presumption was strong based upon BRCA1's gene sequence homology to other genes with a known function, but why not hold the patent applicant responsible for showing actual use in practice? Would that not expand the window in which additional research can be conducted by third parties before they are required to obtain a license to use the gene?

The current usefulness standard in general is that a new product is "not useful *only* when it is incapable of achieving any beneficial function or use in any application and under any consequences."[240] In regards to new chemicals, patents are only to be granted upon the disclosure of some specific utility by the new chemical.[241] In *In re Kirk*, the court found that the application failed to describe a useful invention.[242] The patent application claimed that the new compounds could be converted into something useful, but did not make a claim

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[238] U.S. Patent No. 4,259,444 (emphasis added).

[239] U.S. Patent No. 5,709,999 (emphasis added).

[240] 1 PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 3:4 (2d ed.)

[241] *Id*.

[242] 376 F.2d 936 (C.C.P.A. 1967)

of usefulness regarding the new compounds themselves.[243] It was held that the new compound was not useful in the patent sense because the only use of the new compound was to make other compounds that showed promise in being useful.[244]

The bar is set slightly lower when applying to patent a pharmaceutical drug. Inventors are only required to show *potential* therapeutic use in application.[245] Various types of research that *might* indicate *potential* therapeutic benefits are disclosed in the patent application.[246] Because testing does not necessarily involve experiments that accurately mimic the way in which a pharmaceutical will be used once it hits the market, researchers are often forced to jump to conclusions regarding the effect the pharmaceutical will have, and thus the usefulness requirement is significantly easier to achieve for chemicals if the inventor proposes a pharmaceutical use.

The interests of inventors are kept in mind with both of these standards. Significant effort is expended in developing a new chemical or pharmaceutical drug. It is only right that protection is granted to ensure that this effort is rewarded. Because, testing on humans may pose a risk to the test subject, raising many ethical concerns as a result, it is much harder to obtain sufficient data when testing pharmaceutical drugs than it is to obtain data on new chemicals that can be tested without a live test subject and do not raise the same ethical concerns. It makes sense to loosen the usefulness standard in this case in order to encourage the development of marketable pharmaceuticals. Where do genetic patents fall in relation? A gene sequence has a chemical structure of its own and could be treated as a new chemical, and many genes are eventually put to pharmaceutical use.

Arguably, standard methods of obtaining gene sequences in the lab and accessible databases containing genetic information make it even easier to isolate a gene from DNA than to develop a new chemical using nothing as a template. In other words, researchers do not have as much effort vested when they apply for a genetic patent.

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[243] *Id*.

[244] *Id*.

[245] 1 PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 3:5 (2d ed.)

[246] *Id*.

Regardless, many genes being patented receive more lenient treatment than other pharmaceuticals. As seen in *Myriad*, usefulness is achieved based on homology to the function to known genes with similar sequencing. This means that usefulness may be achieved prior to the development of a pharmaceutical being derived from the gene, and well before the standard applied to pharmaceutical drugs that requires that testing then be conducted on the derived pharmaceutical that may propose a use. If less energy is being expended on isolating genes, and if pharmaceuticals that are not derived from DNA are held to a heightened showing of usefulness, then the standard for genetic patents should be that, at a minimum, research using the *derived pharmaceutical* must be presented in order to show usefulness. Or, better yet, using the logic of *In re* Kirk, gene patents should not qualify as a useful invention when their usefulness comes from creating something else that has a clear use. Patents would then be reserved only for the products derived from the isolated genetic material, and the genetic material itself should be rendered ineligible.

Admittedly, heightening the usefulness standard would have no impact on ethical concerns. It is still up for debate whether DNA, the key to unlocking nature, is something that humans should tamper with at all. Also, whether or not genes are discoveries or inventions, an issue that may be addressed again in the near future, remains unaffected by a heightened usefulness requirement. It is likely, however, that both of these issues are in our rearview and focusing on them would be fruitless in trying to change the future of genetic patenting. So, what impact could a heightened usefulness standard actually have?

A heightened usefulness would have no impact on the underlying principles of patent law. Effectively, all a heightened standard would do is adjust the timing for when reward is received for the fruits of a researcher's labor. Researchers still get their reward, but only upon the showing of an invention that has proven itself useful. That is, a researcher would only be rewarded once it is shown that he has upheld his end of the deal. This does not eliminate the incentive for researchers to invent, and the additional burden in showing actual usefulness is not significant enough to deter companies and institutions from conducting research. A heightened usefulness standard, in reality, only brings the usefulness requirement into

existence. For, as of now, usefulness is not really required at all for genetic patenting.

Undoubtedly, complaints will arise from corporations because some profits will be lost if they are unable to obtain patents prior to developing a pharmaceutical from an isolated gene. This is true. Some profits will be lost. However, those lost profits are the profits that come from licensing genetic patents to outside researchers who may be able to put the isolated genes to use – the lost profits would be those profits that are fueled by the "Big Freeze," by hindering research, and by stunting the growth of innovation. If the goal of patents is to protect innovators, and if an innovation is something new, not obvious, and useful, then corporations will not lose any money earned from patents that comply with this goal. If corporations can put out a product that is of use to society, then they shall receive protection and shall earn the right to profit from the fruits of their labor.

Genetic patents are being granted on a promise that a use will be found. No more promises. A heightened usefulness standard creates an otherwise unopened window of advancement. For, in the time it takes for an individual who isolated a gene to demonstrate the usefulness of it, many other uses could simultaneously be found by many other scientists. Research could flourish as licenses would no longer be needed in order to use a genetic sequence, and the expenditures that would have gone towards a license could now be fed back into research and additional innovation. The incentive to invent would remain, but the "Big Freeze" would be no more.

VI. CONCLUSION

Stemming from the United States Constitution, patents are an integral part of American culture, capitalism, and business. Patents protect the innovative, guaranteeing that they will be rewarded for the inventions they create. Patents are supposed to inspire profit and growth, and ensure that the public will see the benefit. On occasion, the unfortunate truth is that plenty of profits are made, but society does not see the benefit. Instead, patents necessary to further research hinder and delay research – defying the goals of the patent system. Genetic research has led to significant societal contributions in agriculture, as well as in the medical field with the development of new pharmaceuticals. More recent research shows great promise.

However, sometimes research requires collaborative efforts and multiple licenses must be obtained in order to progress. Maybe that is just the price that must be paid to play the game – or maybe the patents that are hindering research should be reconsidered.

Patenting genetic material has raised several issues. Some have contemplated the ethics of tampering with our own genetic material. Some have argued that DNA is naturally occurring, and should not qualify for patent protection at all. As it stands, patents to protect genetic material are constantly being granted, and we are still in the midst of the "Big Freeze." Because of readily available genetic information and streamlined laboratory techniques, serious reconsideration of the nonobvious standard has occurred. This reconsideration may be necessary, and the nonobvious standard may be a real issue that should be dealt with – but it is not the only issue.

The standards for meeting the usefulness requirement are nearly nonexistent when dealing with genetic patents. The requirement is met on credit. A patent applicant need not show that the gene sequence is useful, but merely promise that it might be useful with further research. If patent applicants are held to the burden of actually producing enough data to show a use, the window of opportunity for other researchers to take full advantage of the soon-to-be-patented gene. Likely, the only use the gene has is that it will be used to produce something else, such as a protein that may be used to develop pharmaceuticals. If this is the case, then a patent should be granted on the pharmaceutical, but the gene sequence should remain unpatentable until a direct use is shown. Researchers who find the locations of previously undiscovered gene sequences will still be incentivized, but the incentive will come from inventing something from the genetic material they have replicated. Businesses will oppose this idea. Profits in licensing will be lost, but the integrity of the patent system will remain intact. Sometimes it is necessary to take a step back and ask, "What's the use?"